REMARKS

The above-captioned patent application has been carefully reviewed in light of the non-final Office Action to which this Amendment is responsive. Claims 1-3, 7-9, 12, 15, and 23 have been amended in an effort to more clearly define and particularly point out that which is regarded as the present invention. Claims 17-19 and 28-30 have been canceled. No new matter has been added to the above-captioned application.

Claims 1-34 stand pending. The Examiner has rejected all pending claims on the basis of certain prior art, particularly Killeen et al. (U.S. Patent No. 5,166,051), either taken alone or in combination with either Fruitstone et al. (U.S. Patent No. 4,259,057), Cremins et al. (U.S. Patent No. 4,978,624) or Maimon, et al. (U.S. Patent No. 5,350,693). All pending Claims 1-34 have also been rejected based on 35 USC §112, second paragraph. In addition, Claims 2, 3, 17-19 and 28-30 have been objected to under 37 CFR §1.75(c). The Examiner has also made commentary relating to the Information Disclosure Statements (IDS) previously filed in connection with this pending application, as well as Applicants' priority claim.

Applicants respectfully requests reconsideration of the claimed subject matter and withdrawal of all objections based on the amended and canceled claims and the following comments.

Turning first to the prior art rejections, the Examiner has rejected Claims 1-4, 7-14, 19, 21-25, 30 and 32-34 under 35 USC §102(b) as being clearly anticipated by Killeen et al. (U.S. Patent No. 5,166,051).

The present invention discloses a biosensor comprising a specimen addition part, a cell shrinkage reagent holding part, a marker reagent holding part, a reaction layer, and respective porous materials in a water absorbing part. A liquid specimen is added to the specimen addition part and infiltrated into the cell shrinkage reagent holding part wherein clogging is avoided by making cell components that are included in the liquid specimen shrunk with a cell shrinkage reagent that is held in the cell shrinkage reagent holding part even if the cell components are missing, and

furthermore, the liquid specimen can be infiltrated into the water absorbing part. Thus, a penetration time required to add the liquid specimen to the specimen addition part and infiltrate it into the water absorbing part can be shortened. As a result, an analysis of components included in the liquid specimen can be performed quickly.

On the other hand, Killeen et al. discloses a biosensor, wherein an adhesive strip 18 is provided on a support 10 having reading site apertures 12 (see Figure 1). A detection zone membrane 14 is attached onto the adhesive strip 18 so as to cover the reading site apertures (see Figure 2), and an overlay membrane 16 is set so as to contact with and cover the detection zone membrane 14 (see Figure 3). Furthermore and as described at col. 2, lines 26-35, the instant reference discloses the art making it possible to pass an analysis target through the detection zone membrane 14 and analyze components in a blood specimen by taking out red blood cells via ostium of the detection zone membrane because the crenating agent held in the overlay membrane 16 makes the red blood cells in the blood specimen shrunken and rigid when the blood specimen is added to the overlay membrane 16.

Comparing the present invention with the cited reference, the Killeen reference discloses a biosensor for screening components in a blood specimen through the ostium of membrane, thereby preventing the red blood cells from entering into the detection zone. On the contrary and according to the present application, the cell shrinkage reagent held in the cell shrinkage reagent holding part shrinks the cells and makes the blood specimen developed. Therefore, the red blood cells are not exhausted, but rather are developed to the water absorbing part together with the liquid specimen. Therefore, an entirely different mechanism is employed.

These differences are not trivial and produce several advantages. First, and as noted above, analysis time can be shortened. In the instant reference, the separation of the red blood cells bring the clogging in the detection zone and therefore it takes time for the screened blood plasma to infiltrate into the detection zone. On the other hand and since the shrunk red blood cells are moved together

with the blood plasma, the present invention enables clogging to be avoided altogether, to make the blood specimen infiltrate smoothly and to perform development chromatographically.

Second, the amount of blood sample required for analysis is reduced. According to Killeen, only the blood plasma is developed in the detection zone which accordingly increases the required blood amount. The present application, conversely, uses shrunk red blood cells that are moved together with the blood plasma. As a result, it is possible to decrease the required blood amount because the shrunk red blood cells also contribute to the chromatographic development. Accordingly, there is less burden on a patient, given the small blood amount that is required when a sample is taken.

In addition, the Killeen reference requires a support onto which the biosensor is laid with respective constitutional elements arranged close to each other. At this time, a user must pay attention in order to cover the reading site apertures 12 on the support, making fabrication of the biosensor fairly complex. In the present application, however, the biosensor comprises respective constitutional elements having the same thicknesses and rectangular shapes being placed parallel together, as shown in Figure 1, or comprises constitutional elements having the same shaped flat surfaces being loaded, as shown in Figure 3. As a result, the present biosensor is more compact.

Applicants have herein clarified Claims 1, 12 and 23 by specifying the above-noted features with relation to the differences in mechanism between Killeen et al. and the present invention. Killeen fails to include or suggest a biosensor that includes a carrier for carrying a cell shrinkage agent which causes the cell components of the liquid specimen to shrink so as to develop same to the water absorbing part together with the liquid specimen. Because these features are not present or suggested by the cited Killeen reference as described above, there can be no anticipation under the Statute. It is believed Claims 2-4, 7-11, 13, 14 and 32-34

being dependent thereupon are also allowable for the same reasons. Claims 19 and 30 have been canceled. Reconsideration is therefore respectfully requested.

The Examiner has rejected Claims 5-6, 15-16, 26-27 under USC §103(a) as being unpatentable over Killeen et al. in view of Fruitstone et al. (U.S. Patent No. 4,259,207), Claims 6, 16 and 27 over Killeen et al. in view of Cremins et al. (U.S. Patent No. 4,978,624), and Claim 20 over Killeen et al. in view of Maimon et al. (U.S. Patent No. 5,350,693).

Applicants also respectfully traverse these rejections in toto. First and in order to successfully maintain a "*prima facie*" obviousness rejection under the Stature, each and every essential claimed feature or limitation must be found, or its substantial equivalent, in the cited art, either above or in combination. For a combination to exist, there must be motivation found in the prior art as a whole at the time of the invention to one of sufficient skill. The references cannot be combined as a result of impermissible hindsight (i.e., advance knowledge) of the invention.

Applicants have already discussed the differences between amended Claims 1, 12 and 23 and the primary Killeen reference. The cited reference fails to include or suggest a biosensor that includes a carrier for carrying out a cell shrinkage reagent and having the ability of making (red blood) cell components shrink on at least a part of an area from a specimen addition part for adding a liquid specimen to the reagent holding part of the biosensor. In this manner, the shrunk cells are carried along with the liquid part (plasma) to avoid clogging and to permit smooth infiltration.

The secondary cited references of Maimon, Fruitstone et al. and/or Cremins et al. taken alone or in combination fail to add these essential features and therefore claimed subject matter is missing from the prior art. Each of the previous citations do arguably discuss constituency of certain components but fail to disclose the essential structural differences, discussed infra, that are blatantly absent from the primary reference of Killeen et al. As a result, Applicants believe that a *prima facie*

case of obviousness cannot be maintained by the present rejection and withdrawal of same is respectfully requested.

Turning to the Section 112 rejections, the Examiner has rejected Claims 1-34 under 35 USC §112, second paragraph, for indefiniteness.

Applicants have amended Claims 1, 12 and 23 to clarify the terms noted by the Examiner on pages 4 and 5 of the outstanding Office Action and to provide suitable antecedent basis. Applicants' have also amended Claims 1, 12 and 23 to more clearly describe the chromatographical operation/utilization of the biosensor. Claims 2, 3 and 7-9 have also been amended to correct a minor antecedent basis problem. Finally, Claims 12 and 23 have further been amended to more clearly define the missing steps of the claimed method and to avoid the "gap" noted by the Examiner. To that end, it is believed no new matter has been added. Reconsideration is respectfully requested.

As to the claim objections under 35 USC §1.75(c), Applicants have voluntarily canceled Claims 17-19 and 28-30. Claims 2, 3 now are believed to be in proper form based on the amended Claim 1. It is believed these claims are now in a suitable dependent form and withdrawal of the claim objections is respectfully requested.

With regard to the discrepancy concerning Applicants' priority document, Applicants herein note that the present application was filed as PCT/JP01/04649, and that the priority document 2000-164990 was filed to WIPO and received on July 20, 2001. Pursuant to MPEP §1893.03(c), it is believed this filing to the International Bureau satisfies the requirement for Applicants' priority claim as to the submission of the certified copy. To that end, a copy of the PCT/IB/304 form accompanied the submission of this National Phase application attesting to the submission of the Transmittal of the Priority Document, is attached hereto as Exhibit A.

Finally and with regard to the Information Disclosure Statements, filed 13 May 2002 and 11 February 2003, the Examiner has argued that no concise explanation of the listed 11-505327 and 1,140,462 references have been provided, pursuant to 37 CFR §1.98(a)(3). The Examiner is also objecting to the completeness of the disclosure of the cited 01262470A and 06094718A references.

With regard to 11-505327 reference, Applicants previously cited WO 96/35952 which is a family member thereof in the 13 May 2002 IDS. Though the latter should be adequate, Applicants' herein also attach a copy of the English translation of the '327 reference, as obtained from the JPO website, as Exhibit B.

As to the SU 1,140,462 patent, this reference was cited to Applicants in a corresponding foreign search report. The patent does not have an English equivalent. However, the reference was merely regarded in this report as a Category "A" indicative of state of the art and is believed to only be that of background material with regard to the claimed subject matter.

Regarding JP 1-262470, Applicants herein further attach copies of three (3) English U.S. family members (U.S. Patent Nos. 3,983,059, 3,947,399, 3,862,075) as representing the subject matter of this reference, an English translation of which is also attached hereto as Exhibit C.

Finally, regarding JP 6-94718, Applicants also regard this reference as state of the art as received in a corresponding foreign search report and designated only as Category "A". It is also not regarded as significantly relevant, but should at a minimum be placed in the application file. For the sake of completeness, a copy of the English translation obtained from the JPO database is submitted hereto as Exhibit D.

In summary, it is believed the above-captioned patent application is in an allowable condition and such allowance is earnestly solicited.

If the Examiner wishes to expedite disposition of the above-captioned patent application, he is invited to contact Applicant's representative at the telephone number below.

The Director is hereby authorized to charge any additional fees associated with this communication or credit any overpayment to Deposit Account No. 50-0289.

Respectfully submitted,

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